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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/067,148	05/26/1993	LUC MONTAGNIER	3495.000404	5174

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/067,148	MONTAGNIER ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) ~~45-49~~ is/are pending in the application. 29-31, 39, 40, + 45-49

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) ~~45-49~~ is/are rejected. 29-31, 39, 40, + 45-49

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 06/558,109.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.129(a)

Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 C.F.R. § 1.129(a). Applicant's submission after final filed on 21 January, 2003, has been entered.

Status of the Claims

Applicants' response canceled claims 37, 38, and 41-44 without prejudice or disclaimer and included new claims 45-49. The accompanying amendment did not include a claim appendix. Accordingly, it appears that claims 29-31, 39, 40, and 45-49 are pending in the instant application.

35 U.S.C. § 101

The following is a quotation of 35 U.S.C. § 101 which reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 29-31 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a well-established utility. The claims are directed toward immunological complexes comprising a purified HIV-1 antigen (e.g., p12 or p18) and antibody against said antigen. The disclosure fails to describe the isolation and preparation of said immune complexes. Moreover, the disclosure fails to provide any credible utilities for said immune complexes. It is not readily manifest to the skilled artisan how such immune complexes would be utilized. While there are descriptions of immune complexes being prepared in the prior art, these complexes were designed to mask

immunodominant epitopes in an attempt to induce an immune response against other epitopes. However, no such utility is disclosed in the instant application for the claimed immune complexes.

35 U.S.C. § 112, first paragraph

Claims 29-31 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a well-asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

35 U.S.C. § 112, First Paragraph

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 29-31, 39, 40, and 45-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). Claims 29-31 are drawn toward immunological complexes comprising a purified HIV-1 antigen (e.g., p12 or p18) and specific antibody. Claims 39, 40, and 45-49 are directed toward antibodies specific toward HIV-1 p12, p18, mixtures of antibodies specific for p12 and p25, mixtures

of antibodies specific for p18 and p25, and mixtures of antibodies specific for p12, p15, p18, p25, p36, p42, and p80.

Applicants again traverse the rejection and submit that adequate support exists in the specification for the claimed invention. Applicants assert that the specification teaches detailed procedures for purifying the viral antigens p12, p18, p25, p15, p36, p42, and p80. It was further asserted that the specification teaches using HIV-1 proteins as immunogens for the production of antibodies. Applicants conclude that they were clearly in possession of the claimed antibodies. Concerning the immune complexes, applicants assert that that the specification teaches the preparation of immune complexes formed by patient antisera and viral extracts. It was further asserted that art-recognized methods for preparing immune complexes (i.e., immunoprecipiation) were available at the time of filing. Since patient antisera that reacted with p12, p13, p19, p42, and p80 were identified, applicants conclude that this places the claimed invention within their possession. Applicants' arguments have been duly noted but are not deemed to be persuasive for the reasons of record previously set forth.

As previously noted, the written description requirement under Section 112, first paragraph, stipulates that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *Ralston Purina Company* v. *Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid,* and

Worms, 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter* v. *Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988).

As previously set forth, this rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in **possession** of the claimed HIV-1 antibodies and immunological complexes at the time of the filing date relied upon. **The specification fails to provide any demonstrative evidence that applicants had generated the claimed antibodies or immune complexes.** Moreover, the disclosure only refers to subject matter directed toward a newly isolated virus, the antigens p13, p18, and p25 (refer to disclosure, page 6). The disclosure describes the isolation, purification, and propagation of this virus, designated LAV by applicants. It was further reported that extracts containing p12, p18, and/or p25 were prepared. There was one mention of patient antibodies that displayed reactivity toward the LAV antigens p12, p18, p25, p36, p42, and p80 (refer to page 13 of the disclosure). However, **there was no indication that applicants actually contemplated generating, isolating, and characterizing LAV-specific antibodies.** Moreover, **there is no indication that applicants actually contemplated using these antibodies or immune complexes comprising said antibodies and the appropriate viral antigen.** Accordingly, the skilled artisan would reasonably conclude that applicants were **not** in possession of the claimed invention at the time of filing. Applicants may obviate the rejection by providing scientific evidence demonstrating that the claimed antibodies and immune complexes were actually generated.

37 C.F.R. § 1.132

The declaration filed 23 January, 2003, under 37 C.F.R. § 1.132 is insufficient to overcome the rejection of the claims. Dr. Cohen

asserts that one skilled in the art would be capable of following the teachings of the disclosure to prepare purified viral antigens and antibodies specific thereto. Montelaro *et al.* (1982) was also cited in support of this position. The crux of the rejection is not whether the skilled artisan is capable of purifying viral antigens and making antibodies against said antigens, but whether or not the applicants actually had possession of the claimed invention. It is well-established that an application may be enabled for a particular protocol but still lack an adequate written description of the claimed invention. Such is the case in the instant application. There is nothing in the disclosure to suggest to the skilled artisan that applicants actually prepared the claimed immune complexes or antibodies. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

21 March, 2004